GOVERNMENT OF INDIA
HEALTH AND FAMILY WELFARE
LOK SABHA

UNSTARRED QUESTION NO:389
ANSWERED ON:20.11.2002
DRUG FIXED DOSE COMBINATION
BALIRAM

Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) whether the Government have decided to allow the 4-Drug Fixed Dose Combination for T.B. patients;

(b) if so, by when the notifications are likely to be issued;

(c) whether all New Manufacturers seeking permission for the above Drugs will have to do the Bio-equivalence;

(d) if so, the names of the authorized testing labs;

(e) whether it is also true that these B.E. Reports have to be submitted to DCGI for getting approval; and

(f) if so, the details thereof?

Answer

THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE (SHRI A. RAJA)

(a)& (b) : The matter of Fixed Dose Combination of four Anti-T.B. drugs was examined by drug Technical Advisory Board and DTAB agreed in principle for allowing FDC of four Anti-T.B. drugs, and to suitably modify existing entryno. 229 in the list of prohibited drugs. Issue of Notification is under process.

(c) to (f) : The requirement of bioequivalence study for new manufacturers of Fixed Dose Combination of four Anti-T.B. drugs is under examination. Bioequivalence studies are mainly required for oral dosage forms of new drugs. Based on the expertise and infrastructure available, the B/E reports are considered from number of centers like, Bombay College of Pharmacy, Mumbai, KMK College of Pharmacy, Mumbai, Therapeutic Drug Monitoring Lab, Mumbai, Bio-kinetic Center, Mumbai, Drug Monitoring Research Institute Mumbai, JSS College of Pharmacy, Ooty, NIPER, Chandigarh, PERD Center, Ahmedabad, Nizam`s Institute, Hyderaba Vimta Lab, Hyderabad, Sipra Lab, Hyderabad , RanbaxyResearch Lab, Gurgaon, Zydus Cadila, Ahmedabad, SPARC, Vadodara, Gujarat, College of Pharmaceutical Sciences, Manipal, Karnataka, Torrent Research Center, Ahmedabad and Lambda Therapeutics Ahmedabad.